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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,010	09/26/2006	Jose Maria Garcia Anton	15053.0014USWO	1379

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EXAMINER	
MCCORMICK, MELENIE LEE	
ART UNIT	PAPER NUMBER
1655	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,010	GARCIA ANTON ET AL.	
	Examiner	Art Unit	
	MELENIE MCCORMICK	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8 and 9* is/are pending in the application.

4a) Of the above claim(s) *8 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants remarks with claim amendments submitted 10 April 2008 have been received and considered.

Claims 6-7 have been cancelled.

Claims 8-9 have been added.

Claims 1-5 and 8-9 are pending.

Claims 8-9 have been withdrawn from consideration.

Elections/Restrictions

Newly submitted claims 8-9 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The previously examined claims are drawn to a composition for topical application for treating cellulite. Newly presented claims 8-9 are drawn to method of reducing the harmful or toxic effects of carbonyl species generated in the treatment of cellulite in a subject in need thereof, comprising administering to such subject a composition comprising ingredients with lipolytic and venotonic effects and the tripeptide glycyl-histidyl-lysine and is distinct from the previously examined composition because the originally presented composition could have a use in another method besides the method of reducing the harmful or toxic effects of carbonyl species generated in the treatment of cellulite instantly claimed. . In addition, the method of claims 8-9 are likely to raise non-prior art issues different from those of the previously examined claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim13 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-5 are presented for examination on the merits.

Withdrawn Rejections

The previous claim objection to claim 2 has been withdrawn in view of the amendment to claim 2, which now recites 'are'.

Claims 6-7 have been withdrawn, therefore the previous rejection under 35 U.S.C. 101 is moot.

The previous rejection of claims 6-7 under 35 U.S.C. 112, second paragraph is also rendered moot in view of the cancellation of claims 6-7.

The previous rejection under 35 U.S.C 112, first paragraph (scope of enablement) has been withdrawn in view of the amendment the claims which no longer recite 'prevent'.

Maintained Rejections

Claim Objections

Applicants' amendments to the claims which removed the bullets is noted. It is also noted that Applicants have taken the examiner's suggestion to use letters instead of bullets. Upon considering the amendment, it is noted that the same letters are used to denote different ingredients. In order to avoid any confusion, it is suggested that the letters also be removed. The claims would be more clear without the letters or bullets.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-5 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth in the previous Office Action and for the reasons discussed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta (US 2004/0146439) and Marquart et al. (1988) for the reasons set forth in the previous Office Action and for the reasons discussed below. Please note that claim 4 was inadvertently included with this rejection in the previous Office Action.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta (US 2004/0146439), Marquart et al. (1988), and newuproducts.com in view of Lambers et al. (WO99/29293) for the reasons set forth in the previous Office Action and for the reasons discussed below.

Response to Arguments

35 U.S.C. 112, first paragraph, Written Description

Applicants argue that as described in paragraphs 9-12 of the present application, tripeptide glycl-histidyl-lysine aids in the quenching of reactive carbonyl species (RCS) which are formed in decomposition processes in the cells by means of the application of agents with a lipolytic effect and that no matter which lipolytic agent is administered to accelerate fatty acid decomposition, this acceleration results in the formation of

numerous compounds within the cells, some of which may be harmful or toxic for the cells. Applicants further argue that numerous lipolytic agents are known and that the particular nature of the lipolytic agent is independent of the subject matter of the specification, since the common characteristics for all lipolytic agents are the acceleration of the fatty acid decomposition, and the resulting formation of harmful or toxic reactive carbonyl species as by products. This is not found persuasive. Although based upon the specification and the knowledge in the art at the time of filing, Applicants may be enabled for any of the lipolytic agents, which would result in acceleration of fatty acid decomposition, it is not clear that Applicants had contemplated the use of the various lipolytic agents which are encompassed by the claims. As previously stated, Applicants claims would encompass lipolytic enzymes. Nowhere in the specification as originally filed does Applicant contemplate the use of such enzymes. It would therefore not be clear to one of skill in the art that Applicants were in possession of the instantly claimed invention at the time the application was filed.

The rejection is therefore deemed proper and is maintained.

35 U.S.C. 103(a) Gupta in view of Marquart

Applicants argue that they have unexpectedly and surprisingly found that GHK quenches harmful or toxic aldehydes and other reactive carbonyl species

generated in decomposition processes in cells as a result of the application of agents with a lipolytic effect. Applicants further argue that the cited combination of references does not teach or suggest a composition that reduces the harmful or toxic effects of reactive carbonyl species or a composition comprising a quenching agent of reactive carbonyl species. This is not found persuasive. As previously discussed, Gupta teaches a topical composition that provides body firming, slimming, fat reduction and cellulite reduction which includes caffeine, L-carnitine, Hedera helix extract and Ruscus aeculeatus extract, which are lipolytic ingredients, as instantly claimed (see e.g. [0056] and claim 1). Gupta further teaches that the composition may additionally contain a composition for varicose vein reduction or blood microcirculation improvement, as this would be beneficial for people with a weight problem (see e.g. [0058] and claim 1). Gupta further teaches that such an ingredient includes escin, a venotonic ingredient, as instantly claimed (see .g. [0058]). Gupta further teaches that the composition contains a cosmetically or pharmaceutically acceptable carrier or delivery system, which may include water (see e.g. claims 1 and 16). Gupta further teaches that the composition contains a composition to promote collagen synthesis in the skin, which synergistically enhances the effect of the lipolytic and venotonic ingredients (see e.g. [0058] and claim 1). Although Gupta does not explicitly teach that the composition contains the peptide glycyl-histidyl-lysine, Marquat et al. teach that the peptide glycyl-histidyl-lysine stimulates collagen synthesis in fibroblast cultures (see e.g. entire article and [ages 345=346- Discussion). A person of ordinary skill in the art therefore would have had a reasonable expectation of success in preparing a composition comprising lipolytic and

venotonic ingredients as instantly claimed as well as water, based upon the disclosure of Gupta that it is beneficial to provide treatment for varicose veins and poor microcirculation in combination with treatment for fat reduction and slimming (see e.g. [0058]). A person of ordinary skill in the art would have had a reasonable expectation of success in substituting one of the collagen synthesis promoting compositions taught by Gupta for the glycyl-histidyl-lysine peptide taught by Marquat et al. A person of ordinary skill in the art would have been motivated to do so based upon the disclosure of Marquat et al. that such a peptide stimulated collagen synthesis of skin cells (fibroblasts) and the disclosure of Gupta that such compositions which stimulated collagen synthesis of the skin provided a synergistic enhanced effect with the lipolytic and venotonic ingredients. It therefore would have been obvious to combine the claimed ingredients for the reasons discussed, which are disclosed by Gupa and Marquat. The fact that Applicants may have found another functional effect of the combination does not render the combination non-obvious in light of the teachings of Gupta and Marquat. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

The rejection is therefore deemed proper and is maintained.

103(a) over Gupta, Marquart et al. and newuproducts .com in view of Lambers et al.

Applicants argue that Lambers and newuproducts.com do not cure the deficiencies of Gupta and Marquart and that neither references teaches or suggestes the quenching activity of GHK or the recited amounts of GHK to reduce or quench the harmful or toxic effects of reactive carbonyl species. This is not found persuasive. The teachings of Lambers and newuproducts.com have been discussed in the previous Office Action. In addition, as stated above, the references need not teach the additional functional effect now claimed (the quenching or reducing of harmful or toxic effects of reactive carbonyl species). The ingredients are all known to be useful for treating cellulite. Therefore, the result effective adjustment of the particular amounts of these ingredients would well within the purview of a person of ordinary skill in the art. As previously discussed, this is especially true given the teaching of Gupta that quantities of the active ingredients can be provided as needed (see e.g. claim 17).

The rejection is therefore deemed proper and is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELENIE MCCORMICK whose telephone number is (571)272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melenie McCormick
Examiner
Art Unit 1655

/Patricia Leith/

Primary Examiner, Art Unit 1655